UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. THOMAS L. CROFUT and JUDITH H. CROFUT, individuals d/b/a GOOD FLOW HONEY AND JUICE CO., Defendants.	NO. 07-CV-00996-SS THE UNITED STATES' PRE-HEARING MEMORANDUM AND REPLY TO DEFENDANTS' RESPONSE TO THE UNITED STATES' PETITION FOR CONTEMPT

Plaintiff, the United States of America, respectfully submits this Memorandum in anticipation of the hearing scheduled for September 5, 2008, and in reply to the Defendants' Response to the Plaintiff's underlying Petition for an Order to Show Cause Why Defendants Should Not Be Held In Contempt.

I. INTRODUCTION

On July 30, 2008, this Court granted the Plaintiff's Petition for an Order to Show Cause Why Defendants Should Not Be Held In Contempt, directing the Defendants to respond to the United States' petition and appear for a hearing on September 5, 2008. On August 19, 2008, the Defendants filed their Response. The Defendants admit that they continue to produce juice after the entry of the Consent Decree. Notwithstanding the provisions of Paragraph 4 of the Decree, the Defendants' "deny that such conduct was in violation of the terms of the Consent Decree."

The Defendants state it is their "understanding that they would be enjoined from producing juice *unless* they diligently worked to accomplish the requirements of" Paragraphs 4(A) - (D). In addition, the Defendants indicate that their efforts to comply with the law and the

Consent Decree have been hampered because their expert has been assisting his wife, who is ill. Finally, the Defendants suggest that the government's action is unnecessary because of the "freshness and quality" of their juice. As detailed herein, nothing in the Defendants' Response excuses their continuing failure to comply with the law and the explicit terms of the Consent Decree. The Defendants' "understanding" of the plain language of the Consent Decree is simply not credible.[1]

II. ARGUMENT

A. Defendants' Response Fails to Provide Any Justification For Their Failure To Comply With The Consent Decree and FDA's June 24, 2008 Letter

In an attempt to justify their failure to comply with the requirements of the Consent Decree, the Defendants first assert that they "understand" Paragraph 4 of the Decree to merely require them to "diligently work" to accomplish the requirements of Paragraphs 4(A) - (D). However, the plain language of Paragraph 4 unequivocally states that the Defendants are "hereby permanently restrained and enjoined . . . from receiving, processing, preparing, packing, holding, or distributing juice at or from Defendants' juice processing plant . . . unless and until" the requirements set forth in Paragraphs 4(A) - (D) are satisfied. The directive of Paragraph 4 could not be clearer. See United States v. Alcoa, Inc., 533 F.3d 278, 286 (5th Cir. 2008) (noting that courts "should read consent decree terms by their plain meaning."). Nothing in Paragraph 4 remotely indicates that the Defendants may avoid the mandatory cessation of operations by

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[1] Given the Defendants' admission that they have been operating their juice business after the entry of the Consent Decree, the government does not anticipate the need to call any fact witnesses during the hearing on September 5, 2008; however, should the Court desire testimony regarding the underlying inspection as well as the observations of the Defendants' continued business operations, Reynaldo R. Rodriguez, Jr., the Director of FDA's Dallas District Office and R. Todd Lorenz, a Consumer Safety Officer from the Dallas District Office, will be available to testify.

"diligently working" toward satisfying the requirements of Paragraphs 4(A) - (D). If that was the standard, then Paragraph 4 would contain plain language to that effect. In addition, the Defendants' position would lead to an absurd result, for it would have the practical effect of permitting the Defendants to continue operating in a manner contrary to law almost indefinitely.

To justify their disregard for the Consent Decree, the Defendants also assert that their efforts to comply with the Consent Decree were hampered because their Hazard Analysis Critical Control Point ("HACCP") expert was tending to his ailing wife. While the United States is sympathetic to the circumstances faced by the Defendants' expert, this in no way excuses the Defendants' refusal to cease operations upon entry of the Decree, as required by Paragraph 4. Given the explicit requirements of Paragraph 4, the Defendants should have either engaged a new expert or accepted the fact that their facility would have to remain out of operation longer than they had anticipated. The Defendants, however, chose an easier option – ignore the clear requirements of the Consent Decree.

The Defendants' Response is also noteworthy for its complete absence of any explanation for their continuing refusal to cease operations after receiving a letter from the United States Food and Drug Administration ("FDA") on June 24, 2008, wherein FDA directed the Defendants to cease receiving, processing, preparing, packing, holding or distributing any juice. Pursuant to Paragraph 11 of the Consent Decree, the Defendants were required to "immediately" comply with FDA's directive. Their failure to do so, coupled with their refusal to even acknowledge FDA's correspondence in their Response, is yet another troublesome and inexcusable aspect of the Defendants' behavior as it constitutes a blatant disregard for the plain requirements of this Court's Order.

B. The Defendants' Recent Submission of a HACCP Plan for FDA Review Does Not Excuse Their Continued Violation of the Consent Decree

The Defendants' Response appears to suggest that the United States' Petition for Contempt is unwarranted because the Defendants' expert has now submitted a HACCP plan to FDA for review. This position, however, ignores not only the plain language of the Consent Decree, but the gravity of the Defendants' ongoing refusal to comply with its provisions. Although the Defendants' expert submitted a HACCP plan on August 13, 2008, with respect to the Defendants' citrus juice,[2] this submission came more than five years after the HACCP regulation became applicable to the Defendants, four years after FDA notified the Defendants that they were required to make necessary improvements to comply with the HAACP regulation, eighteen months after FDA issued the Defendants a Warning Letter detailing their noncompliance with the HACCP regulation, eight months after the United States filed its Complaint in this matter, and three months after the Consent Decree was entered by the Court.

Moreover, the recent submission of this single citrus juice HACCP plan for review by FDA by no means vitiates the Defendants' obligation to cease operations. As detailed above, Paragraph 4 of the Consent Decree requires the Defendants to cease operations until all four components of Paragraph 4 are satisfied. Although the submission of the HACCP plan by the Defendants' expert may indicate compliance with Paragraphs 4(A) and 4(B), it does not satisfy the certification requirement of Paragraph 4(C). Most importantly, the mere submission of a single HACCP plan for FDA review in no way satisfies Paragraph 4(D) of the Consent Decree. Under Paragraph 4(D), the Defendants must have received written notification from FDA that their HACCP plan appears to satisfy the requirements of Paragraphs 4(A) - (C) of the Consent

[2] As of this filing, the Defendants have not submitted a HAACP plan for any other type of juice that they produce.

Decree, the Food and Drug Act, and 21 C.F.R. § 120. The Defendants have not received any such notification.[3]

Furthermore, although Paragraph 6 of the Consent Decree contemplates that Defendants will be permitted to resume operations during a 120-day implementation period that commences after all four requirements of Paragraph 4 are satisfied, the United States requested in its underlying Petition that the Court eliminate the 120-day implementation period as a consequence for Defendants' contumacious failure to comply with Paragraphs 4 and 11 of the Consent Decree. Specifically, given the Defendants' conduct, Plaintiff has asked that requirements of Paragraphs 6(A) and 6(B), regarding implementation of the HACCP plan – like the requirements of Paragraph 4, regarding the origination of that plan – should be fully met to FDA's satisfaction before the Defendants are permitted to resume operations.

C. The HACCP Regulation Was Implemented to Protect the Public Health.

Notwithstanding the Defendants' cavalier attitude concerning the need for federal regulation of their production facility, it is beyond question that the HACCP regulation was implemented in 2001 in an effort to ensure the safety of the nation's juice and limit the potential hazards associated with the consumption of untreated juice. See Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6138, 6182 (Jan. 19, 2001) (the "Final Rule"). The development of the HACCP regulation took several years to draft and incorporated extensive input from scientists and industry representatives following the issuance of a "Proposed Rule" in 1998. See Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing

[3] Consistent with Paragraph 4(D) of the Consent Decree, representatives from FDA's Center for Food Safety and Applied Nutrition ("CFSAN") are currently reviewing Defendants' August 13, 2008 submission.

and Importing of Juice; Food Labeling: Warning Notice Statements; Labeling of Juice Products; Proposed Rules, 63 Fed. Reg. 20450 (Apr. 24, 1998). As detailed in the Final Rule, the production of juice without proper monitoring and sanitation controls creates optimal conditions for the proliferation of *Salmonella* and other pathogenic microorganisms. FDA estimates that there are approximately 2,430 cases of *Salmonella* illness each year attributable to the consumption of contaminated juice. See Final Rule, 66 Fed. Reg. 6138, 6182.

Although the Defendants apparently consider themselves immune from the dangers inherent in the production of fresh squeezed juices, their blind faith in the safety of their food products does not entitle them to ignore important regulatory requirements implemented to protect the public health. While implementation of the HACCP regulation in 2001 required manufactures to upgrade their facilities and processes to protect the public health, the regulation gave small businesses, like the Defendants, a one-year grace period, until January 21, 2003, to comply with the regulation.[4] See 21 C.F.R. § 120.1(b). FDA has now spent more than five years attempting to get the Defendants to comply with the regulation. The United States now asks the Court to put an end to Defendants' recalcitrance.

III. CONCLUSION

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[4] In paragraph 10 of their Response, the Defendants incorrectly assert that the juice HACCP regulation did not apply to their production of juice until January 2004. Pursuant to 21 C.F.R. § 120.1(b)(1), small businesses (those employing fewer than 500 persons) became subject to such regulation on January 21, 2003. In accordance with 21 C.F.R. § 120.1(b)(2), "very small" businesses were not subject to the regulation until January 20, 2004. The Defendants, however, do not meet the definition of a "very small" business because their annual sales (both in dollars and units sold) exceed the limits set forth in the regulation. As such, although paragraph 10 of Defendants' Response states that they qualified as a '"very small"' business because they "sold less than 100,000 units of juice," this statement is contradicted by Defendant Judith Crofut's September 18, 2003 affidavit, wherein she states: "In the first 6 months of 2003, we have manufactured approximately 290,000 units of juice and our annual sales are approximately $1.1 million." A copy of Defendant Judith Crofut's signed affidavit is attached hereto as Exhibit 1.

For the foregoing reasons, and those stated in its Petition, the Plaintiff respectfully requests that this Court find the Defendants in contempt and issue an order requiring them to cease production in accordance with Paragraphs 4 and 11 of the Decree, with such cessation continuing until the requirements of Paragraphs 4, 6(A), and 6(B) are met to FDA's satisfaction; award Plaintiff conditional fines, its attorneys' fees, FDA's investigational expenses, and all other costs incurred by the government that relate to the Defendants' violation of the Consent Decree; and grant any such other relief as the Court deems just and proper. A proposed Order is attached.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing THE UNITED STATES' PRE-HEARING MEMORANDUM AND REPLY TO DEFENDANTS' RESPONSE TO THE UNITED STATES' PETITION FOR CONTEMPT was filed electronically via the ECF system which serves upon counsel of record for Defendants as recorded below, on this 25th day of August, 2008. Notice has been electronically mailed to:

John L. Foster of Minton, Burton, Foster & Collins, P.C.
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s/ Katherine E. Beaumont
KATHERINE E. BEAUMONT

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. THOMAS L. CROFUT AND JUDITH H. CROFUT, individuals d/b/a GOOD FLOW HONEY AND JUICE CO., Defendants.	)	NO. 07-CV-00996-SS ORDER OF CIVIL CONTEMPT

Upon consideration of the Petition filed by Plaintiff, United States of America, for an Order to Show Cause why Defendants should not be held in contempt for violation of the Consent Decree of Permanent Injunction ("Decree") entered by this Court on May 6, 2008, the matter being fully briefed and the Court considering the entire record herein,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

I. This Court has jurisdiction over the subject matter and over the parties to this action.

II. The Defendants are in civil contempt of the Decree entered by this Court on May 6, 2008, as alleged in Plaintiff's Petition for an Order to Show Cause Why the Defendants Should Not Be Held In Civil Contempt for violation of this Court's Decree.

III. The Defendants must immediately halt all receiving, processing, preparing, packing, holding, or distributing juice unless and until the requirements of Paragraph 4(A) - (D), 6(A), and 6(B) are met to the satisfaction of the United States Food and Drug Administration.

IV. If, at any time after entry of this Order, the Defendants violate any provision of the Decree, the Defendants shall pay to the United States Treasury $1,000.00 per each day of continued violation upon written notice from FDA and without further order from this Court.

V. The Defendants shall reimburse the United States for its attorneys' fees, the investigational expenses of FDA, and all other costs incurred by the government that relate to the Defendants' violation of the Consent Decree, within fifteen (15) calendar days after the Defendants' receipt of a statement from Plaintiff setting forth these fees and costs.

VI. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order of Civil Contempt and for the purpose of granting such additional relief as may be deemed necessary and appropriate.

Dated this _____ day of _____, 2008.

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United States District Judge